K070864

JUN - 1 2007

510(K) SUMMARY

BonePlast® QS Calcium Sulfate Bone Void Filler

Preparation Date: May 16, 2007

Applicant/Sponsor: Biomet Osteobiologics
100 Interpace Parkway
Parsippany, NJ 07054
Establishment Registration Number: 1450662

Contact Person: Debra Bing
Director of Regulatory Affairs

Proprietary Name: BonePlast® QS Calcium Sulfate Bone Void Filler

Common Name: Injectable Bone Void Filler

Classification Name: Filler, Bone Void, Calcium Compound (MQV/888.3045)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Calcigen™ S Bone Void Filler - K013790, June 11, 2002 (Biomet Orthopedics, Inc., Warsaw, IN)
- MIIG II™ - K024336, March 04, 2003 (Wright Medical Technology, Inc., Arlington, TN)
- MIIG SR® – K060011, February 27, 2006 (Wright Medical Technology, Inc., Arlington, TN)

Device Description: BonePlast QS Bone void filler is a sterile calcium sulfate powder, which is supplied dry. When mixed with sterile setting solution intra-operatively, it becomes an injectable filling material for use in non-load bearing procedures. The filler is biogradable and resorbs in approximately eight to twelve weeks, depending on the defect size, based on animal studies.

Intended Use: BonePlast® QS is indicated to be injected into open voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. BonePlast® QS Bone Void Filler is indicated only for bone voids or gaps that are not intrinsic to the stability of the bone structure (i.e., the extremities, spine, and pelvis). The device is limited to be used in posterolateral spinal fusion procedures only.

Summary of Technologies: The technological characteristics (materials, design sizes, and indications) are similar to or identical to that of the predicate devices to which substantial equivalence is claimed. The product is also identical in chemistry and formulation to the predicate device Calcigen™ S Bone Void Filler (K013790).

Non-Clinical Testing: The information presented demonstrates that the BonePlast® QS Calcium Sulfate Bone Void Filler is substantially equivalent to currently marketed predicate devices. Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Osteobiologics
% Palaniswamy Vijay, MPH, Ph.D.
Manager, Applied Regulatory Technology
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581-0587

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Re: K070864
Trade/Device Name: BonePlast® QS Calcium Sulfate Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV
Dated: May 16, 2007
Received: May 17, 2007

Dear Mr. Vijay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or on the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BIOMET

INDICATIONS FOR USE

510(k) Number (if known): K070864

Device Name: **BonePlast® QS Calcium Sulfate Bone Void Filler**

Indications for Use:

BonePlast® QS Bone Void Filler is indicated to be injected into open voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. BonePlast® QS Bone Void Filler is indicated only for bone voids or gaps that are not intrinsic to the stability of the bone structure (i.e., the extremities, spine and pelvis). The device is limited to be used in posterolateral spinal fusion procedures only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070864